TANYX Proeffect

A NEW CONCEPT IN PAIN TREATMENT

Effective against **PAIN**:

Muscle | Joint | Menstrual Cramps

TANYX® USER MANUAL

Congratulations on your recent purchase of TANYX®, a Pain Relief System with advanced technology. Please read the instruction manual carefully and familiarize yourself with the operational system of this product.
Virtually everyone at some point in life has had some type of a physical, work, or sports-related pain due to discomfort caused by repetitive motion of muscles and/or joints.
In most situations the use of TANYX® eliminates the necessity of taking oral pharmaceutical medications that may have numerous contraindications and side effects.
TANYX® Pain Relief System is based on a TENS device and designed to be a compact, disposable, wireless, user-friendly version of any current TENS devices in the market today.
TANYX® is a revolutionary electronic system designed to apply electrical stimulation of low intensity directly to the body to provide symptomatic relief of minor muscle aches and pains and mild muscle tension associated with stress.
The device is used until the battery is depleted, when the device should be disposed appropriately, according to the local laws for battery disposal. If TANYX® is left turned on but not in direct contact with the skin's surface, the device will automatically turn off after 5 minutes to preserve battery life.

ABOUT TENS

Transcutaneous Electrical Nerve Stimulation (TENS) provides a non-invasive and non-medicated means of controlling or reducing pain. "Transcutaneous" means on or within the surface of the skin without any penetration of the skin. Mild electrodes apply safe and comfortable electrical waves transcutaneous and an alternative method of pain control becomes available to the user.
TENS has been used medically for several decades and there are several explanations on how the application of TENS controls pain. In simple terminology, TENS is thought to manage or control pain by either interfering with the neural transmission of pain to the brain (Gate Control Theory), and/or enhancing the release of the natural chemical substances that reduce pain which are normally produced by the body (Endorphin Theory), increasing circulation and providing relaxation to the muscles by causing a local paranesthesia.
There are several scientific publications in medical journals that have documented and supported the effectiveness of TENS as a non-medicated or complementary method of pain control.
Pain is a protective mechanism and its suppression may eliminate its value as an indicator of the progression of a condition. Therefore, it is recommended that your pain condition be diagnosed by a physician before the use of your TANYX® .
Contact your physician if the pain does not change or if there is a worsening in the nature of it.

INDICATIONS

For temporary pain relief, TANYX® can be used for the following indications:

- Chronic tendinitis;
- Lumbago (Back pain);
- Osteoarthritis and arthrosis;
- Dysmenorrhea (See precautions);
- Shoulders pain, related to tension and back superior area pain ;
- Other chronic muscular pains at superior extremities, (arms) and inferior extremities, (legs).

USER PROFILE

TANYX® can be used by individuals 11 years of age and older with a minimum 5 years of intensive reading skills who can read and understand alphanumeric characters, with a minimum reading visual imperfection. There is no need to have any special experience in TENS treatment. It can be used also on children younger than 11 years old, upon doctor's recommendation and proper adult supervision.

CONTRAINDICATIONS

TANYX® should not be applied:
- On the breast;
- On irritated skin.
- On open wounds;
- On the head front region (forehead);
- On carotid artery (neck front and side region);

TANYX® should not be used:
- By patients with unknown cause of pain;
- By patients carrying metallic prostheses;
- By patients carrying pacemaker or defibrillator;
- Should not be used simultaneously with high frequency surgical equipment's;
- On painful conditions caused by appendicitis, stomach pain, hepatitis, etc.;
- During pregnancy (electric stimulation safety on pregnant is not established).

WARNINGS

Do not use TANYX® while sleeping.

Do not use TANYX® at explosive environment.

When battery is depleted, it should not be replaced.

Do not immerse the device into water and don't use it on wet environment.

Avoid using TANYX® near radio frequency equipment, since it may alter its operation.

If a rash occurs, stop TANYX® usage and contact a physician to evaluate TANYX® application.

Be careful using your TANYX® where the electromagnetic compatibility could interfere with its operation.

Keep this device out of the reach of children. However, it may have pediatric indication under adult supervision.

Do not apply TANYX® on the chest because the stimulation could cause rhythmic disturbances on the heart.

Do not use the product near short waves equipment or micro waves because this can affect product functioning.

Do not take the battery apart or submit to a short circuit, disassemble it, deform it, heat it up or put the battery near a direct flame.

The usage of this device is not appropriate in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide gases.

Any action above can cause the battery to overheat, explode and cause injury.

Do not use the device while operating machines or during any other activity where electric stimulation could expose you to risk or cause injuries.

Do not apply TANYX® on damp skin or with cream, ointment or any chemical substances. Before applying TANYX®, be sure that the site of application is dry and clean.

Electronic monitoring equipment such as Electrocardiograph, monitor or Electrocardiograph alarm may not operate correctly if used conjointly with TANYX®.

Consult a physician to evaluate TANYX® usage if you suffer or have been diagnosed with Epileptic incidents, malignant tumor, convulsions, blockade of the cardiac branch, high fever or acute inflammatory diseases.

Turned off the TANYX® device before attaching or removing the electrodes to the body. Don't handle TANYX® on the skin when is turned on, because a small, uncomfortable electrical stimulus may be felt when the electrodes come into contact whit the skin.

PRECAUTIONS

Isolated cases of skin irritation may occur if or when electrodes are placed at the same location continuously for a long period of time.
Burns caused by the electrodes may occur due to its inappropriate handling, caused by erosion or gel pad removal of the electrode.
TANYX® usage during labor or physical exercise, if sweaty, can interfere in its effectiveness and performance.
In the event of a cardiac disease diagnosis, follow your physician's recommendations.
Ensure you are not pregnant before using TANYX® for period cramps and or dysmenorrhea.
To avoid contaminations of skin diseases by users or the spread of transmissible diseases, the manufacturer suggests not to share the device with the objective to prevent contamination among users.
The manufacturer suggests that the device must not be shared, to avoid contamination among users by possible skin diseases.

INSTRUCTIONS OF USE

Application of TANYX®

1. Remove the sticker of each gel pad showing "DISCARD";
2. Adhere one gel pad onto each TANYX® electrode. After fixed, remove the stickers of each gel pad showing "PROTECTION". Do not discard these gel pad stickers, since they should be replaced on each gel pad after the use of the device, for its conservation;
3. Clean and dry the skin application area of TANYX®. If necessary, shave the hairs from the area (when they are in excess). The application should be at the pain site or as close to it as possible;
4. If the surface of the gel is not moist and sticky, wet it slightly with the tip of your finger moistened;
5. Apply the TANYX® device in the area and lightly press the gel pad areas to assure complete adhesion to the skin surface;
6. Use your TANYX® as described in the following item (TANYX® operation and adjustment). Each session should last 20 minutes, sufficient amount of time to relieve the pain. If necessary, it can be applied for longer as there is no restriction to the time or quantity of applications;
7. After the end of the session, turn off the device;
8. After turned off, carefully remove your TANYX® from the application area, detaching the gel pads from the skin;
9. Replace the pads on each gel (written "PROTECTION") and repack your TANYX® back into the blister.

The life of the gel pads on the electrodes varies depending upon skin conditions, duration of stimulation and area of application.
Consult your physician or physiotherapist for the best place to apply and use your TANYX®.
Must be used in 60 days after gel pad is applied onto the electrode.

TANYX® OPERATION AND ADJUSTMENT

To turn on your TANYX®, press and hold the ON button (⏻) for 3 seconds. The LED light will turn on and it will continue to blink once every second, but it will start signal a blinking

emission after intensity selection (L; M; H).

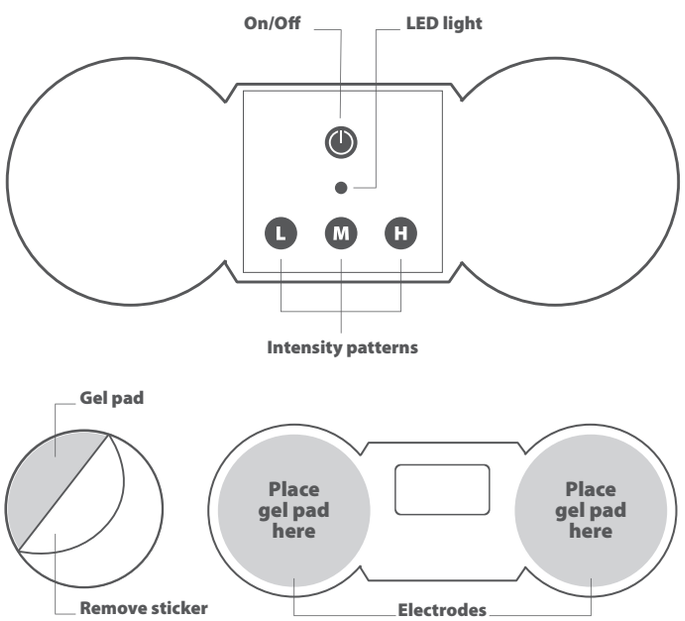
Your TANYX® offers two choices of stimulation modes:

• **CONVENTIONAL** (produces a continuous tingling sensation) and;
• **PULSE** (the stimulation is produced in cycles that alternates between on/off every 3 seconds).

Both modes have pre-programed pulsation patterns and width wave intensity; however, it allows an individual control of intensity using the LOW (L), MEDIUM (M) and HIGH (H) patterns. The choice of which mode to use depends of the nature, location and characteristics of the pain; as well as personal comfort and preference.
The intensity should be controlled by the patient's comfort level. If the muscle contraction is troubling, the adhesive position should be slightly changed until the uncomfortable contractions disappear and only a tingling sensation remains. The intensity may be increased by the patient from low to medium or high, depending on the patient's comfort. The device should remain in the application area for 20 minutes, which is sufficient time to control pain. Remaining for that time, the device can be used 30 times, since the battery lasts up to 10 hours. One or two daily applications are sufficient, but the product can be used as long as desired, because there is no risk of overdose, even if it is used for more than 20 minutes. It also can be used as many times as desired per day.
For its first use, TANYX® is set for CONVENTIONAL mode. To change from CONVENTIONAL mode (Constant) to PULSE mode (Alternate) or vice versa, press ON button (⏻) for 1 second and the unit will change from one mode to another.
To change the INTENSITY level, PRESS LOW (L), MEDIUM (M) or HIGH (H) button for 1 second.
To turn off your TANYX®, PRESS and HOLD ON/OFF button (⏻) for 3 seconds.

NOTE: *If TANYX® is turned ON and not placed in contact with the skin surface it will AUTOMATICALLY turn OFF after 5 minutes to preserve the battery life. TANYX® unit has a predetermined battery life. When the TANYX® battery is within 30 minutes of expiration the LED light will begin to BLINK in a rapid sequence to alert you. The battery is expected to work continuously up to 10 hours depending on how the unit is used and kept.*

When the battery has expired, the LED light will go out and the TANYX® unit will stop functioning, at which time the unit should be properly disposed of.



MAINTENANCE AND STORAGE

Product should be disposed appropriately, according to the local laws for battery disposal.

TECHNICAL SPECIFICATION

Pulse Frequency: 55Hz
Pulse Width: 80 µs
Adjustable intensities: L; M; H
Operation range: (Charge of 500 ohm): 40 mA a 50 mA (peak current)
Remark: By software control, chosen intensity takes 2s to arrive to the respective voltage after turning the device on.
Modes: Conventional or Pulse
Minimum duration: 10 hours
Energy source: 3-volt lithium cell CR2025
Operation temperature: -25ºC ~ 40ºC
Protection degree: IP22
Device classified as transit operable
Storage: Keep in a dry place under temperature between -5ºC ~ 40ºC

EMC SPREAD SHEET

Standard	Tension	Observations		
CISPR 22	3 Vdc	Preview Measurement Detector 1		Peak detector
		Final Measurement Detector 1		Quasi-Peak Detector (if necessary)
Class	Distance	Polarization	Tension	Operator
B	3 m	V/H	3vdc	Wagner Mello
Obs: The relation between the limits of 10m and 3m is stablished throug the formula E2=E1+20log[d1/d2]. Where: E is given in dBµV/m and d in meters. Result in a variation of 10,5dB in the limit of the eletric field for d=3m				

Standard	Tension		Level (kV)	Criterion
IEC 61000-4-2	3Vdc	Air	± 8	A
			±15	A

Standard	Tension	Polarization	Level	Frequency Rang	Modulation	Criterion
IEC 61000-4-3	3Vdc	H/V	8 V/m	80 MHz a 2,5 GHz	AM, 80%, 1KHz	A
			15 V/m			A
Monitoring: Through video camera and operation verification during the test with the support of an oscilloscope pausing during the tests.						

Standard	Frequency (Hz)	Level (A/m)	Criterion
IEC 61000-4-8	50 e 60	3	A
		30	A

Validity: 36 months from the date of manufacture.

TROUBLE SHOOTING

1. The LED light has stopped flashing: the LED light may be blown out or the battery could be depleted.

2. Once battery life is depleted: simply dispose of your TANYX®, according to the local laws for battery disposal.

3. In case your product does not emit signals: make sure it is turned "ON" and elected intensity has been selected.

4. When the LED light is blinking very quickly: an indication the TANYX® battery is ending. That happens when the battery is close to its last 30 minutes of use.

5. Uncomfortable electrical stimulation felt on the skin when the product is ON: moisten the gel pad a little and press it in area for a better fixation, avoiding this sensation.

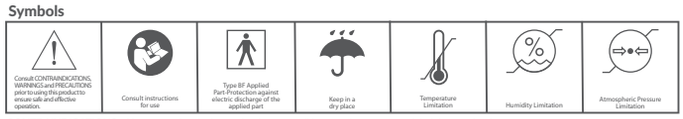
6. The gel pads are not adhering: moisten the gel pad by running your wet finger over it. Make sure the skin is not too oily, if so, remove the excess oil from the skin. Make sure if the area has many body hair, if so, remove them for a better fixation.

7. If your device stops functioning after 5 minutes: maybe the device is not recognizing that it is connected to the skin of your body. Check the adherence of the gel pad. If the problem persists, switch the intensity M or H on the intensity button of your TANYX®.

Packing content

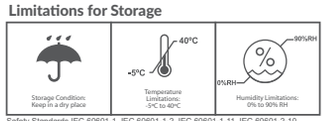
01 Tanyx® / 02 - Gel Pad / 01 - User Manual
OBS: Disposable product. It shouldn't be submitted to any kind of cleaning or sanitation process.

Symbols

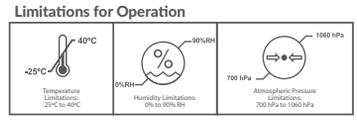


CONTRAINDICATIONS - Never use the device under these conditions as they may result in injury or death.
WARNINGS - Avoid the labeled hazardous situations, which could result in death or serious injury.
PRECAUTIONS - Avoid the labeled hazardous situations, which may result in minor or moderate personal injury or may damage the device.

Limitations for Storage



Limitations for Operation



Safety Standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-10

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TANYX
Proeffect

A NEW CONCEPT IN PAIN TREATMENT